DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Ser
Food and Drug Ad

M3634

San Francisco District
1431 Harbor Bay Parkwa
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-39605

April 7, 2000

John L. Visser, Owner
Visser Ranch
15605 Avenue 208
Strathmore, California 93267

WARNING LETTER

Dear Mr. Visser:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your calf ranch on March 14 through 21, 2000, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On January 11, 2000, you consigned a calf (identified by USDA laboratory report number 366260) to be slaughtered for human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this calf revealed the presence of sulfamethoxazole in the muscle at 1.80 parts per million (ppm) and in the liver at 0.31 ppm, as well as streptomycin in the kidney at 1.20 ppm and in the liver at 0.57 ppm. There is no established tolerance level for sulfamethoxazole in calves. Presently, the tolerance level for streptomycin in calves is 2.00 ppm in the kidney and 0.50 ppm in other tissues.

Your firm has established a history of delivering animals for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of January 13, 2000, through February 24, 1987, your firm delivered four calves and one cow with violative levels of

drug residues. Also, during the period of July 3, 1989, through March 13, 1986, your firm delivered [redacted] calves that were found to be CAST positive.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

The drug Sulfamethoxazole and Trimethoprim tablets that you use to treat your calves is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v), and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with approved labeling. Your veterinarian prescribed Sulfamethoxazole and Trimethoprim at a dosage of one tablet per 100 pounds of body weight and warned against releasing animals for slaughter for food use within thirty-five days. Failure to adequately segregate treated calves is likely the cause of the illegal residues found in the animal you sold for food use. Failure to adhere to your veterinarian's prescribed label instructions presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

You are frequently the individual who delivers, or offers for introduction into interstate commerce, calves intended for slaughter for food. As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act if such animals are adulterated. To avoid future illegal residue violations you should take precautions such as:

1. implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2. implementing a system to determine from the source of the animal whether the animal has been medicated, and if so, with what drug(s); and,

3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially

hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal, then it should be clearly identified and sold to a grower as a medicated animal.

You have failed to provide written treatment records to growers and other raisers notifying them of drug treatments you have administered to animals you sold to them. You are administering Gentamicin Sulfate Injectable into heifer calves you are custom raising for dairymen and you are throwing away treatment records prior to notifying them of any past drug treatments.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify our Fresno resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Robert B. Johnson

District Director
San Francisco District

cc: [redacted]